AMENDMENT UNDER 37 C.F.R. § 1.111

Appln. No.: 10/544,112

## <u>REMARKS</u>

Attorney Docket No.: Q88453

Claim 1 and 6 have been amended to recite internal pores based on the disclosure at page 8, lines 28-29 that the porous fibers of the present invention have holes in inner parts of fibers.

Entry of the above amendment is respectfully requested.

## **Obviousness Rejection**

Claims 1-4, 6-8 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson et al. (US 6,596,296).

In response, Applicant notes initially that the Examiner indicates that the fiber surface texture can be controlled according to the method described in Nelson citing the following paragraph:

Another surprising discovery was that the surface texture of the finished fiber could also be controlled by appropriate choices of solvent and polymer systems. The inventors have produced fibers with surface textures that vary from smooth, to veloured, to longitudinally grooved as shown in FIGS. 11A-11C. These changes in surface texture have practical applications to cell growth in providing surfaces with greater adhesive properties in the case of the veloured texture, and better contact guidance in the case of the longitudinally grooved fibers. All of the changes in mechanical properties and surface texture significantly affect the release kinetics of therapeutic agents.

Thus, Applicant considers that Nelson is only directed to the fiber surface feature in this regard.

Therefore, Applicant has amended the claims to more clearly distinguish the present invention from those suggested by Nelson.

AMENDMENT UNDER 37 C.F.R. § 1.111 Attorney Docket No.: Q88453

Appln. No.: 10/544,112

More specifically, Applicant have clarified that the fibers of the present invention have internal pores.

Applicant submits that the basis for this amendment can be found in the following passages in the specification.

"However, by using this method, a fiber structure formed has pores only on fiber surfaces, and it is difficult to make porous so far as the inner fibers" (Background Art, page 2, lines 30-32)

. . .

"Porous fibers of the present invention express fibers having isolated holes and/or continuous holes on surfaces and in inner parts of fibers." (Best Mode for Carrying Out the Invention, page 8, lines 28-29, emphasis added)

The examiner also states that selecting a common form of monosaccharide, specifically glucose, would have been obvious to one of ordinary skill in the art. However, Applicants do not consider that this allegation is reasonable in the light of Nelson, such as the following description beginning at column 8, line 23.

In this invention, therapeutic agents may include drugs, proteins, peptides, mono- and di-saccharides, polysaccharides, glycoproteins, DNA, RNA, viruses, or other biological molecules of interest. The term therapeutic agent in this invention also includes radioactive materials used to help destroy harmful tissues such as tumors in the local area, or to inhibit growth of healthy tissues, such as in current stent applications; or markers to be used in imaging studies.

It should be noted that Nelson takes a lot of paragraphs to explain therapeutic agents that can be used in his invention. See columns 10-17. Nelson illustrates a wide variety of therapeutic

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Appln. No.: 10/544,112

agents and among them, many cytokines and polynucleotides are exemplified specifically.

Under such circumstances, Applicant considers that it is not reasonable to single out glucose

from among other bioactive molecules and continue on to present arguments based on the

selected compound. Further, Applicant considers that it is unreasonable to conclude that the

porosity of at least 5% is inherent to the fiber of Nelson.

Thus, Applicant submits that the present invention is not obvious over the cited art, and

withdrawal of this rejection is respectfully requested.

Conclusion

In view of the above, reconsideration and allowance of this application are now believed

to be in order, and such actions are hereby solicited. If any points remain in issue which the

Examiner feels may be best resolved through a personal or telephone interview, the Examiner is

kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue

Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any

overpayments to said Deposit Account.

Respectfully submitted,

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7